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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,273	12/26/2000	Julie R. Korenberg	9002-014-999	4861

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/749,273	KORENBERG ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 12, drawn to a nucleic acid encoding an EHOC-1 polypeptide, a vector comprising said nucleic acid as well as a cell comprising said vector, classified in class 435, subclass 325.

II. Claims 10-12 and 45, drawn to a nucleic acid probe, a kit for detecting mutations and single stranded DNA primers for amplification, classified in class 536, subclass 24.31.

III. Claim 14 and 15, drawn to an antisense oligonucleotide, classified in class 536, subclass 24.5.

IV. Claims 16-23, drawn to an isolated EHOC-1 polypeptide, classified in class 530, subclass 350.

V. Claims 24-26 and 30, drawn to an antibody that specifically binds to a determinant on an EHOC-1 polypeptide, classified in class 530, subclass 381.7.

VI. Claim 29, drawn to a composition comprising a ribozyme, classified in class 435, subclass 24.5.

VII. Claims 31, 32 and 34-36, drawn to a transgenic animal which expresses an exogenous EHOC-1 gene, classified in class 800, subclass 8.

VIII. Claim 33, drawn to a transgenic animal comprising an antisense DNA, antisense to EHOC-1, classified in class 800, subclass 8.

IX. Claim 37, drawn to a method for identifying nucleic acids encoding EHOC-1 protein, classified in class 435, subclass 6.

X. Claim 38, drawn to a method to identify compounds which bind to EHOC-1 polypeptide, classified in class 435, subclass 40.51.

XI. Claim 39, drawn to a method for detecting the presence of a human EHOC-1 polypeptide on a cell surface, classified in class 435, subclass 7.1.

XII. Claims 40 and 41, drawn to a method for diagnosing a predisposition to a disorder, classified in class 435, subclass 6.

XIII. Claim 42, drawn to a method for deterring the onset of symptoms, classified in class 514, subclass 1.

XIV. Claim 43, drawn to a method for introducing changes at human chromosome locus 21q22.3, classified in class 435, subclass 455.

XV. Claim 44, drawn to a method for supplying wild-type EHOC-1 gene function to a cell, classified in class 514, subclass 44.

XVI. Claim 46, drawn to a method for detecting one or more EHOC-1 alleles in a sample, classified in class 435, subclass 6.

Claims 27 and 28 link(s) the inventions of Groups III and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s)

application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is unrelated to Inventions II-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is drawn to a nucleic acid encoding EHOC-1, a vector comprising the nucleic acid and a host cell comprising said vector. This invention is unrelated to Inventions II-VIII, because the different inventions are drawn to chemically and structurally different products, such as probes, polypeptides, antibodies, ribozymes and transgenic animals). Additionally, Invention I is unrelated to Inventions IX-XVI because Invention I is drawn to a product (a nucleic acid, as well as a vector a cell comprising the nucleic acid), while Inventions IX-XVI are drawn to methods which do not require the nucleic acid of invention I for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

3. Invention II is unrelated to Inventions I and III-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention II is drawn to a probe, primers and kit for detecting mutations in the EHOC-1 gene,. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, polypeptides, antibodies, ribozymes and transgenic animals. Additionally, Invention II is unrelated to Inventions IX-XVI because Invention II is drawn to a product (probe, primers and kit, while Inventions IX-XVI are drawn to methods which do not require the probe/primers/kit of invention II for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

4. Invention III is unrelated to Inventions I, II and IV-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention III is drawn to antisense oligonucleotides and compositions comprising the oligonucleotides. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, primers, polypeptides, antibodies, ribozymes and transgenic animals. Additionally, Invention III is unrelated to Inventions IX-XVI because Invention III is drawn to a product (antisense oligonucleotides), while Inventions IX-XVI are drawn to methods which do not require the oligonucleotides of invention IIII for their operation and which have distinct

desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

5. Invention IV is unrelated to Inventions I-III and V-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention IV is drawn to an EHOC-polypeptide. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, probes, antisense oligonucleotides, antibodies, ribozymes and transgenic animals. Additionally, Invention IV is unrelated to Inventions IX-XVI because Invention IV is drawn to a product (an EHOC-polypeptide), while Inventions IX-XVI are drawn to methods which do not require the polypeptide of invention IV for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

6. Invention V is unrelated to Inventions I-IV and VI-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention V is drawn to an antibody which specifically recognizes EHOC-1 polypeptide. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, probes, antisense oligonucleotides, ribozymes and transgenic animals. Additionally, Invention V is unrelated to Inventions IX-XVI because Invention V is drawn to a product (an

EHOC-1 specific antibody), while Inventions IX-XVI are drawn to methods which do not require the antibody of invention IX for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

7. Invention VI is unrelated to Inventions I-V and VII-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention VI is drawn to a ribozyme. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, probes, antisense oligonucleotides, antibodies and transgenic animals. Specifically regarding the difference between antisense oligonucleotides and ribozymes it is noted that ribozymes are catalytic RNA molecules (while antisense oligonucleotides are not). Additionally, Invention VI is unrelated to Inventions IX-XVI because Invention VI is drawn to a product (a ribozyme), while Inventions IX-XVI are drawn to methods which do not require the ribozymes of invention VI for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

8. Invention VII is unrelated to Inventions I-VI and VIII-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention VII is drawn to a transgenic animal which expresses a transgenic EHOC-1 polypeptide. This invention is unrelated to the other Inventions, because the different

inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, probes, antisense oligonucleotides, antibodies, ribozymes and different transgenic animals. Specifically regarding the difference between inventions VII and VIII. The transgenic animals of Inventions VII have been engineered to produce an exogenous EHOC-1polypeptide, while Invention VIII is drawn to a transgenic animal that expresses an antisense molecule (which inhibits EHOC-1 expression). Additionally, Invention VII is unrelated to Inventions IX-XVI because Invention VII is drawn to a product (an transgenic animal), while Inventions IX-XVI are drawn to methods which do not require the polypeptide of invention VII for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

9. Invention VIII is unrelated to Inventions I-VII and IX-XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention VII is drawn to a transgenic animal which expresses an antisense molecule. This invention is unrelated to the other Inventions, because the different inventions are drawn to chemically and structurally different products, such as nucleic acids encoding EHOC-1, probes, antibodies, ribozymes and different transgenic animals. Specifically regarding the difference between inventions VII and VIII. The transgenic animals of Inventions VII have been engineered to produce an exogenous EHOC-1polypeptide, while Invention VIII is drawn to a transgenic animal that expresses an antisense molecule (which inhibits EHOC-1 expression). Additionally, Invention VIII is unrelated to Inventions IX-XVI because Invention VIII is drawn

to a product (an transgenic animal), while Inventions IX-XVI are drawn to methods which do not require the polypeptide of invention VIII for their operation and which have distinct desired effects (such as identifying compounds, diagnostic methods, treatments and making genetic alterations). Therefore, the Inventions are distinct and restriction is proper.

10. Inventions IX-XVI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods that require different materials and have different functions and desired effects. For instance, Invention IX is drawn to a method for identifying nucleic acids encoding EHOC-1 protein; Invention X is drawn to a method to identify compounds which bind to EHOC-1 polypeptide; Invention XI is drawn to a method for detecting the presence of a human EHOC-1 polypeptide on a cell surface; Invention XII is drawn to a method for diagnosing a predisposition to a disorder; Invention XIII is drawn to a method for deterring the onset of symptoms; Invention XIV is drawn to a method for introducing changes at human chromosome locus 21q22.3; Invention XV is drawn to a method for supplying wild-type EHOC-1 gene function to a cell; and Invention XVI is drawn to a method for detecting one or more EHOC-1 alleles in a sample. Therefore, the Inventions are distinct and restriction is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Additionally, because these inventions are distinct for the reasons given above and the search required for each Group is distinct (e.g., the searches are not coextensive). Therefore, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
AU 1635

DAVE T. NGUYEN
PRIMARY EXAMINER